AF

Attorney Docket No. 10123/03501 (03-210)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Delaney et al.
Serial No.	:	10/668,629
Filing Date	:	September 23, 2003
For	:	Mid-Stream Flushing Adapter Assembly
Art Unit	:	3728
Confirmation No.	:	2181
Examiner	:	Jerrold D. Johnson

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By: Oleg F. Kaplun Reg. No. 45,559 Date: June 1, 2007

TRANSMITTAL

In response to the Notification of Non-Compliant Appeal Brief mailed on May 21, 2007, transmitted herewith please find a revised Appeal Brief for filing in the above-identified application. No fees are believed to be required. However, the Commissioner is hereby authorized to charge the **Deposit Account of Fay Kaplun & Marcin, LLP NO. 50-1492** for any additional required fees. A copy of this paper is enclosed for that purpose.

Respectfully submitted,

Dated: June 1, 2007

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PATENT
Attorney Docket No.: 10123 - 03501

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	)	
	)	
Delaney et al.	)	
	)	
Serial No.: 10/668,629	)	Group Art Unit: 3728
	)	
Filed: September 23, 2003	)	Examiner: Jerrold D. Johnson
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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

In support of the Notice of Appeal filed February 2, 2007, and pursuant to 37 C.F.R. § 41.37, Appellants present their appeal brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 1 - 21 in the final Office Action dated September 26, 2006. The appealed claims are set forth in the attached Claims Appendix.

1. Real Party in Interest

This application is assigned to Boston Scientific Scimed, Inc., the real party in interest.

2. Related Appeals and Interferences

There are no other appeals or interferences which would directly affect, be directly affected by, or have a bearing on the instant appeal.

3. Status of the Claims

Claims 1 - 21 stand rejected in the Final Office Action. The final rejection of claims 1 - 21 is being appealed. Claims 22-25 have been withdrawn from consideration and will therefore not be addressed in this appeal brief.

4. Status of Amendments

All amendments submitted by the Appellants have been entered.

5. Summary of Claimed Subject Matter

The present invention, as recited in independent claim 1, describes a protective package 10 for an elongated medical device 14. *Specification*, p. 7, lines 26 - 29, Fig. 1. The package 10 comprises a protective sheath and a hydration opening 19. *Id.* at p. 8, lines 13 -15, Fig. 1. The protective sheath includes a lumen sized to receive a body of the elongated medical device. A first end 30 of the sheath is adapted to receive a distal end of the elongated medical device and a second end 32 of the sheath is adapted to receive a proximal end of the elongated medical device. *Id.* at p. 8, lines 5 - 8, Fig. 1. The hydration opening 19 is disposed between the first and second ends of the sheath. *Id.* at p. 8, lines 21 -23, Fig. 1.

The present invention, as recited in independent claim 15, describes a catheter kit comprising a catheter, a tubular enclosure 12 having first and second ends 30,32 and a hydration opening 19. *Id.* at p. 8, lines 5 - 8, Fig. 1. The catheter has a shaped distal tip 36. *Id.* at p. 9, lines 23 - 26. The tubular enclosure 12 has a length and an inner diameter corresponding, respectively, to a length and outer diameter of the catheter. *Id.* at p. 8, lines 2 - 4. The first end 30 of the tubular enclosure 12 is adapted to receive the shaped distal tip 36. The second end 32 of the tubular enclosure 12 is adapted to receive a proximal end of the catheter. The hydration opening 19 extends into an interior of the tubular enclosure 12 between the first and second ends 30,32 thereof. The hydration opening 19 is positioned so that a desired proportion of flow thereinto is directed toward the first and second ends 30,32. *Id.* at p. 8, lines 21-25.

The present invention, as recited in independent claim 21, describes a protective package 10 for removably receiving an elongated medical device 14. *Id.*, p. 7, lines 26 - 29, Fig. 1. The package 10 comprises a protective sheath and a hydration opening 19. *Id.* at p. 8, lines 13 -15, Fig. 1. The protective sheath includes a lumen sized to tightly fit a body of the elongated medical device to be received therein. A first end 30 of the sheath is adapted to receive a distal end of the elongated medical device and a second end 32 of the sheath is adapted to receive a proximal end of the elongated medical device. *Id.* at p. 8, lines 5 - 8, Fig. 1. The hydration opening 19 is disposed between the first and second ends of the sheath so that fluid supplied to the sheath via the hydration opening is provided to the first and second ends of the sheath. *Id.* at p. 8, lines 21 -25, Fig. 1.

6. Grounds of Rejection to be Reviewed on Appeal

I. Whether claims 1 - 9, 12, 13 and 15 - 17 are unpatentable under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,569,106 to Ullman et al. ("Ullman").

II. Whether claims 1 - 7, 9 - 14 and 21 are unpatentable under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,588,588 to Samuels.

III. Whether claims 8 and 15 - 20 are unpatentable under 35 U.S.C. § 103(a) as obvious over Samuels in view of Ullman.

IV. Whether claims 1, 3, 6 - 9, 12, 13, 15, 16 and 19 are unpatentable under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 3,861,395 to Taniguchi.

V. Whether claim 4 is unpatentable under 35 U.S.C. § 103(a) as obvious over Taniguchi in view of U.S. Patent No. 4,805,611 to Hodgkins.

VI. Whether claims 1, 3 - 9 and 11 - 13 are unpatentable under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,258,072 to Weinberger.

VII. Whether claims 1, 3 - 9, 11 - 13, 15, 15, 19 and 20 are unpatentable under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,427,114 to Colliver et al. ("Colliver").

7. Argument

I. The Rejection of Claims 1-9, 12, 13 and 15-17 Under 35 U.S.C. § 102(b) as Anticipated by U.S. Patent No. 6,569,106 to Ullman et al. Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 1 - 9, 12, 13 and 15 -17 were rejected under 35 U.S.C. 102(b) as being anticipated by Ullman. *9/26/06 Office Action*, p. 3. Ullman discloses a medical guide wire containment device consisting of a housing which receives and retains one or more guide wires. *Ullman*, Abstract. A leading tip of the guide wire is inserted into an isolation chamber in the housing via a funnel. *Id.* at col. 4, lines 49 - 52. The leading tip follows a fixed spiraling guide preventing entanglement of the guide wire while being inserted into the isolation chamber. *Id.* at col. 5, lines 13 - 16. A lagging tip of the guide wire remains exposed so that a user may pull the guide wire from the housing for reuse. *Id.* at col. 5, lines 34 - 37.

B. Ullman Does Not Disclose a First End of a Sheath Adapted to Receive a Distal End of an Elongated Medical Device with a Second End of the Sheath Adapted to Receive a Proximal End of the Elongated Medical Device as Recited in Claim 1

Claim 1 recites a protective package for an elongated medical device comprising "a protective sheath including a lumen sized to receive a body of the elongated medical device, wherein *a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of elongated medical*

device" and "a hydration opening disposed between the first and second ends of the sheath."

In the final rejection, the Examiner states that Fig. 4 of Ullman shows a protective package for an elongated medical device including a protective sheath (i.e., the fixed spiraling guide 27) and a hydration opening, as recited in claim 1. *9/26/06 Office Action*, p. 3. Appellants respectfully submit that neither the isolation chamber 13 nor the fixed spiraling guide 27 of Ullman is a protective *sheath* "wherein a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of the elongated medical device," as recited in claim 1.

The Examiner asserted that Fig. 4 of Ullman shows a protective package for an elongated medical device including a protective sheath (*i.e.*, the fixed spiraling guide 27) and a hydration opening, as recited in claim 1. *9/26/06 Office Action*, p. 5. Appellants respectfully disagree with the Examiner's assertion. Appellants submit that neither the isolation chamber 13 nor the fixed spiraling guide 27 of Ullman constitutes a protective *sheath* "wherein a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of the elongated medical device," as recited in claim 1. The Examiner relied on the statement in col. 3, ll. 29-30 that the container of Ullman may be employed, with some modification apparent to those skilled in the art, to house catheters. *9/26/06 Office Action*, pp. 5-6. Ullman provides no mention of what these modifications may be. Ullman seems to suggest that the container would be similar to the isolation chamber 13. Perhaps this statement alludes to changes in the dimensions of the structures which will receive

the catheter (*e.g.*, the opening into which the end of the catheter will be inserted). However, this is pure speculation and there is no basis for any suggestion that such a modified chamber would bear any more resemblance to a sheath than the isolation chamber 13.

Furthermore, although the Examiner stated that Ullman "discloses a structure which meets the definition of sheath, particularly with respect to the function of a sheath of a blade," the Examiner did not apply this definition to the components of the device of Ullman. *9/26/06 Office Action*, p. 6. It is respectfully submitted that the term sheath does not encompass any structure into which an item may be inserted. That is, a parking garage is not a sheath for a car. Rather a sheath is a "case for a blade...or other instrument *to which it fits closely*." (Webster's Third International Dictionary, 1986). As noted in the Examiner's definition, the function must also resemble that of a sheath of a blade, particularly to snugly hold an item by fitting closely. If there is one thing a sheath does not do, it does not allow the end of the item inserted to float about freely. The reason a sheath fits a blade snugly is self-evident, making clear the characteristic all sheaths have in common: that the item to be received therein is received snugly.

The Examiner stated that the fixed spiraling guide 27 is a sheath as claimed. *9/26/06 Office Action*, p. 3. However, Ullman states only that the guide 27 "establishes a fixed pathway to ensure the guide wire 16 will spiral in a selected manner without entanglement." *Ullman*, col. 5, ll. 14-16. Fig. 4 shows this guide 27 as a coiled wall which will engage only a leading tip and a radially outer side of the wire 16 inserted into the device 10. That this guide 27

is not a sheath is made clear from Fig. 4 which shows that a width of a proximal portion of the passage through which the wire 16 will be inserted is significantly smaller than a width of the passage defined by the guide 27 – several times smaller. Thus, it is respectfully submitted that it is improper to infer that the space within the guide 27 closely fits the wire 16. In addition to the increased width of this space within the guide 27, it is noted that Ullman provides absolutely no disclosure in its entirety of the size or shape of this space in a direction perpendicular to the plane of Fig. 4 (*i.e.*, a width of the chamber 13). Furthermore, the guide 27 ends at an open central chamber which leaves the distal portion of the wire 16 completely uncontained. Thus, Appellants respectfully submit that the spiraling guide 27 is not a sheath as recited in claim 1.

Furthermore, the Examiner states that the isolation chamber 13 is suitable to receive an entire guide wire 16 encompassing both its distal and proximal ends. *9/26/06 Office Action*, p. 6. However, it is noted that this suggestion is contrary to the disclosure of Ullman. In fact, Ullman states that "the wire is pushed all the way in [the chamber] until a small amount, such as about 1-2 cm, remains external to the membrane." *Ullman*, col. 2, ll. 60-62. A lagging tip 16a is never received by the chamber 13 so that the wire may be easily removed from the chamber 13. The Examiner stated that "the funnel portion [18-20] is suitable to receive the end of the guide wire or catheter entirely within the funnel portion, and yet still allow easy removal of the guide wire or catheter from the package." *9./26/06 Office Action*, p. 7. The Examiner did not explain how the guide wire would be removed from the isolation chamber 13 if the tip 16a were not external to the chamber 13 and it remains unclear how a user would pull the guide wire 16

from the chamber 13 when the tip 16a is located within the chamber 13. As stated previously, if the Examiner implied that, while within the funnel portion, the lagging tip of the guide wire 16 could still be grasped for removal therefrom, this indicates clearly that this funnel portion also does not constitute a sheath. That is, it clearly does not fit the item inserted therein closely. As in the case of a sheath for a blade, such increased width allowing access is the very thing a sheath is designed to prevent. Thus, it is respectfully submitted that neither the chamber 13, the funnel portion thereof, or the guide 27 (or any combination of these elements) constitutes a sheath as recited in claim 1.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 1 and claims 2, 4, 7, 9 and 12 - 13 which depend directly or indirectly therefrom.

Claim 15 recites a catheter kit comprising "a catheter having a shaped distal tip" in combination with a tubular enclosure having a length and an inner diameter corresponding, respectively, to a length and outer diameter of the catheter" and "a first end of the tubular enclosure being adapted to receive the shaped distal tip" and "a second end of the tubular enclosure being adapted to receive a proximal end of the catheter" in combination with "a hydration opening extending into an interior of the tubular enclosure between the first and second ends thereof, the hydration opening being positioned so that a desired proportion of flow thereinto is directed toward the first and second ends." Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 15 and claims 16

and 17 which depend directly therefrom.

C. Ullman Does Not Disclose a Protective Assembly Adapted to Maintain a Desired Shape of the Distal End as Recited in Claim 3

Claim 3, which depends directly from claim 1, recites "a protective assembly disposed at the first end of the sheath, the protective assembly being adapted to maintain a desired shape of the distal end." In the final rejection, the Examiner stated that the funnel 18 disclosed in Ullman is disposed at a first end of the sheath and maintains a desired shape of the distal end of the elongated medical device (*i.e.*, the guide wire 16). *9/26/06 Office Action*, p. 3. Appellants respectfully submit that neither the funnel 18 nor any other structure of the device 10 in Ullman may be considered "a protective assembly" as recited in claim 3.

Ullman specifically states that the funnel 18 "acts as a transition structure to enable a healthcare provider to easily insert the guide wire 16 into an entry port, such as the entry ports 21-23, of the isolation chambers 13-15." *Ullman*, col. 4, lines 52-55. The funnel 18 simply guides the guide wire 16 into the isolation chamber 13. Also, as stated above, the tip 16a remains exposed from the funnel 18. While this allows the provider to grasp the tip 16 to pull the guide wire 16 from the isolation chamber 13, the funnel 18 in no way protects the tip 16a, or any portion, of the guide wire 16.

Furthermore, a shape of the funnel 18, which is shown in Fig. 4 of Ullman, does not maintain a desired shape of the distal end of the elongated medical device. Initially, Ullman

never discloses that the distal end, or any end of the guide wire 16, has a preformed shape which is integral to its function or requires maintenance. In any case, the structure of the funnel 18 is completely unsuitable for maintaining the shape of an end of the guide wire 16. The leading end may contact the funnel 18 and be directed into the isolation chamber 13 when the guide wire 16 is inserted therein, and the lagging tip (tip 16a) is exposed with the funnel 18 surrounding it, as shown in Fig. 2. As made clear previously, the funnel 18 never encloses or encases the proximal end of the guide wire 18 or protects the shape thereof. At the same time, the distal end of the guide wire 16 is free floating in the large open space of the isolation chamber 13. Neither the funnel 18 nor any other structure in Ullman maintains a shape of any portion of the guide wire 16. Thus, it is respectfully submitted that Ullman neither discloses nor suggests a "protective assembly being adapted to maintain a desired shape of the distal end," as recited in claim 3.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 3 for these further reasons.

D. Ullman Does Not Disclose a Protective Assembly Adapted to Prevent Damage to a Curvature of the Distal End of the Elongated Medical Device as Recited in Claim 6

Claim 6, which depends from claim 3, recites that "the protective assembly is adapted to prevent damage to a curvature of the distal end of the elongated medical device." In the final rejection, the Examiner stated that this recitation of claim 6 was disclosed in Ullman.

9/26/06 Office Action, p. 4.

The Appellants respectfully submit that the funnel 18 does not prevent damage to a curvature of the distal end, or any portion, of the elongated medical device. As noted above, the funnel 18 is meant to facilitate insertion of the guide wire 16 into the isolation chamber 13 by directing the leading tip of the guide wire 16 toward a chamber port 21 at a center of the funnel 18. *Ullman*, col. 4, ll. 49-55, Fig. 2. However, the funnel 18 is in no way adapted to prevent damage to a curvature of the guide wire 16, if it even possessed a curvature to begin with. For example, as understood by those of skill in the art, as the guide wire 16 is advanced toward the funnel 18, the distal end engages the funnel 18 at an angle (*e.g.*, substantially perpendicular to a surface of the funnel 18) and/or with enough force, the funnel 18 causes the guide wire 16 to bend guiding it toward the opening. Once inserted into the isolation chamber 13, the distal end of the guide wire floats freely therein while the proximal end extends out of the funnel 18. Thus, any curvature of either end of the guidewire is unprotected by either the isolation chamber 13 or the funnel 18 and it is respectfully submitted that Ullman neither discloses nor suggests a protective assembly "adapted to prevent damage to a curvature of the distal end of the elongated medical device," as recited in claim 6.

Appellants respectfully request therefore that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 6 for these further reasons.

E. Ullman Does Not Disclose a Sheath Adapted to Contain a Catheter with a Shaped Distal Tip as Recited in Claim 8

Claim 8, which depends from claim 6, recites a sheath "adapted to contain a catheter with a shaped distal tip." In the final rejection, the Examiner stated that this recitation of claim 8 was disclosed in Ullman. *9/26/06 Office Action*, p. 4.

Though not cited as a reference in the rejection of claim 8, the Examiner cites U.S. Patent No. 3,606,001 to Talonn as extrinsic evidence that one of ordinary skill in the art would modify the funnel 18 of Ullman to contain a catheter with a shaped distal tip. *Id.* Talonn shows a cardiac catheter package consisting of an elongated tubular housing portion 17 sealed at a distal end and having a removable cap 18 on a proximal end which seals a catheter in the housing portion 17. *Talonn*, col. 2, lines 33 - 44, Figs. 1, 2.

Appellants respectfully submit that Ullman does not disclose a sheath and specifically does not disclose a sheath adapted to contain a catheter with a shaped distal tip. It is submitted that Ullman specifically teaches away from such an arrangement as its goal is to simply prevent the guide wire from becoming entangled while facilitating its retrieval by providing a path along which substantially all of the guide wire will slide. Thus, one skilled in the art would not be motivated to adapt a portion of this path to a specifically shaped distal end as this would complicate the insertion and removal of the guide wire from the isolation chamber. It is noted Ullman never discloses or suggests that the isolation chamber 13 is suitable to receive any catheter and never suggests that it is suitable to receive a guide wire 16 or any other structure

having a shaped distal tip. Also, the funnel 18 of Ullman is not adapted to contain a catheter with a shaped distal tip. That is, the funnel 18 does not, in fact, even contain the guide wire 16, because the tip 16a is exposed in the opening thereof. Furthermore, Ullman does not disclose that either the funnel 18 or the opening thereof is shaped to complement the guide wire 16. Appellants also respectfully submit that it remains unclear how one of ordinary skill in the art would apply the teachings of Talonn to the funnel 18 of Ullman. That is, Talonn does not include any funnel-shaped portion. In fact, the cap 18, which is sized to complement the housing portion 17, completely covers the catheter, which is contrary to the teaching of the tip 16a remaining exposed in Ullman. Ullman specifically states that the tip 16a remaining exposed serves a predefined purpose (*i.e.*, allows the provider to grasp the guide wire 16 and pull it from the isolation chamber 13). Thus, it is respectfully submitted that Ullman (even in view of Talonn as extrinsic evidence) does not disclose or suggest that "the sheath is adapted to contain a catheter with a shaped distal tip," as recited in claim 8.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 8 for these further reasons.

II. The Rejection of Claims 1 - 7, 9 - 14 and 21 Under 35 U.S.C. § 102(b) as Anticipated by U.S. Patent No. 6,588,588 to Samuels Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 1-7, 9-14 and 21 were rejected under 35 U.S.C.

102(b) as anticipated by Samuels. *9/26/06 Office Action*, p. 8. Samuels discloses an adapter that converts medical guidewire packaging into a reusable storage device. *Samuels*, Abstract.

B. Samuels Does Not Disclose a Hydration Opening Disposed Between the First and Second Ends of the Sheath as Recited in Claim 1

Claim 1 has been recited above. In the final rejection, the Examiner stated that Samuels discloses a hydration opening (*i.e.*, the adapter 10, disposed between the first and second ends). *9/26/06 Office Action*, p. 8.

Appellants respectfully submit that Samuels neither discloses nor suggests "a hydration opening disposed between the first and second ends of the sheath." Samuels describes an adapter kit for enabling the reuse of guide wire packaging. *Samuels*, col. 1, ll. 6-8. That is, the system of Samuels is directed to facilitating reinsertion of a guide wire into packing from which it had previously been removed. The kit includes a leading opening 44 and a trailing opening 48. *Id.*, Fig. 1. An adapter 10 connecting the openings 44 and 48 includes a funnel 24 for receiving one or more guidewires 60. The guidewire 60 is inserted into the tube 40 via the adapter 10, winding around the tube 40 until the guidewire 60 has been fully inserted therein. *Id.* at Fig. 3. At no point does Samuels teach or suggest that the adapter 10 is suitable for receiving fluid or that fluid inserted thereinto would hydrate the tube 40. In fact, Samuels states that "[a]fter the guidewire is reinserted into the packaging tube, the adapter 10 may be removed...and the bridge connector may be reinserted to close the loop of the packaging tube." *Samuels*, col. 3,

lines 40-44.

It is respectfully submitted that Samuels does not disclose a hydration opening disposed between a first end 42 and a second end 46 of the packaging tube 40. The first end 42 of Samuels receives a distal end of the guidewire, specifically where the inner end of the guidewire stops at maximum insertion. The second end is a new opening through which the guide wire is inserted. Samuels includes no disclosure in its entirety of a hydration opening disposed between these two ends on the packaging tube 40, let alone on any part of the packaging as a whole.

The Examiner states that a port 30 on the adapter 10 is usable as a hydration opening, and that further evidence of this use is provided in U.S. Patent No. 6,375,006 to Samuels ("'006 patent"). The '006 patent describes a flexible pipe 12 having a sealed end 14 and an open end 16 with a nozzle 20 attached thereto. The '006 patent includes several features that allow fluid to be maintained in the pipe 12. For example, an elbow portion 30 is angled upwards to prevent fluid from leaking; a clamp 22 allows the pipe 12 to retain an upward curling shape to maintain fluid; etc. Even assuming the port 30 of Samuels may be used as a hydration opening (which Appellants do not concede), Samuels describes a "typical single hoop packaging tube" lacking the hydration retention features disclosed in the '006 patent, further evidencing that Samuels would not include a hydration opening.

Furthermore, it is never disclosed or suggested that the nozzle 20 is disposed between "first and second ends" of the pipe 12. In fact, this would be contrary to the disclosure

of the '006 patent which repeatedly describes the apparatus as having one open end and one sealed end, which teaches away from the present invention. Further, the combination of these references would be improper, because Samuels teaches two open ends, whereas the '006 patent teaches only one open end. Thus, it is respectfully submitted that neither Samuels nor the '006 patent discloses or suggests "a hydration opening disposed between the first and second ends of the sheath," as recited in claim 1.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 1 and claims 2, 4, 5, 7 and 9 - 14 which depend therefrom.

Claim 21 recites a protective package for removably receiving an elongated medical device, comprising "a protective sheath including a lumen sized to tightly fit a body of the elongated medical device to be received therein, a first end of the sheath being adapted to receive a distal end of the elongated medical device and a second end of the sheath being adapted to receive a proximal end of the elongated medical device" and "a hydration opening disposed between the first and second ends of the sheath so that fluid supplied to the sheath via the hydration opening is provided to the first and second ends of the sheath." Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 21.

C. Samuels Does Not Disclose a Protective Assembly Disposed at the First End of the Sheath Adapted to Maintain a Desired Shape of the Distal End as Recited in Claim 3

Claim 3 has been recited above. In the final rejection of claim 3, the Examiner stated that the above recitation of claim 3 was disclosed in Samuels. *9/26/06 Office Action*, p. 8.

Appellants respectfully submit that neither the adapter 10 nor any other structure of the device in Samuels may be considered "a protective assembly" as recited in claim 3. As noted above, the adaptor 10 simply facilitates reinsertion of a guidewire into a previously opened packaging tube 40. Specifically, Samuels states that

> [t]he joining configuration of the adapter ends and the packaging tube ends prevents a medical guidewire from getting stuck on the junctions between the packaging tube 40 and the adapter 10 during insertion.

Samuels, col. 3, lines 37 - 40. At no point does Samuels disclose or suggest that any portion of the adapter 10 is adapted to maintain a desired shape of a shaped distal end of any structure. Essentially, the adapter 10 is a conduit which simply expands the ends 46 and 48 of the packaging tub 40 to allow the guidewire to be inserted thereinto. *Samuels*, col. 3, lines 5 - 12. It is unclear how an inside of the adapter 10 is a protective assembly which is adapted to maintain a desired shape of a distal end of the guidewire, as the Examiner has suggested. Samuels does, however, suggest that the adapter 10 may be enlarged to accommodate several guidewires. *Samuels*, col. 3, lines 50 - 55. However, enlarging the adapter only relates to increased-diameter guidewires and would not maintain the shapes thereof. Thus, it is respectfully submitted that

Samuels neither discloses nor suggests "a protective assembly disposed at the first end of the sheath, the protective assembly being adapted to maintain a desired shape of the distal end," as recited in claim 3.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 3 for these further reasons.

D. Samuels Does Not Disclose a Protective Assembly Adapted to Prevent Damage to a Curvature of the Distal End as Recited in Claim 6

Claim 6 has been recited above. In the final rejection of claim 6, the Examiner stated that the above recitation of claim 6 was disclosed in Samuels. *9/26/06 Office Action*, p. 8.

In view of the above description of the adapter 10 and the description of Samuels, it remains unclear how the adapter 10 is adapted to prevent damage to a curvature of any portion of the guidewire, and, in particular, the distal end. No such function or feature is described in this reference. Thus, it is respectfully submitted that Samuels neither discloses nor suggests a protective assembly "adapted to prevent damage to a curvature of the distal end of the elongated medical device," as recited in claim 6 and Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) for these further reasons.

III. The Rejection of Claims 8 and 15-20 Under 35 U.S.C. § 103(a) as Obvious over Samuels in View of Ullman Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 8 and 15-20 were rejected under 35 U.S.C. 103(a) as obvious over Samuels in view of Ullman. *9/26/06 Office Action*, p. 10. The Examiner stated that Samuels discloses the invention substantially as claimed except that the elongated medical device is a catheter, but that Ullman discloses a guidewire package for use with catheters. *Id.*

B. The References Do Not Disclose a Sheath Adapted to Contain a Catheter With a Shaped Distal Tip as Recited in Claim 8

Claim 8 has been recited above and discussed with reference to Samuels and Ullman. Specifically, claim 8 depends from and therefore includes all the limitations of independent claim 1. Claim 8 depends from claim 6 which depends from claim 3 which have been recited above and discussed with reference to Ullman and Samuels. Specifically, neither reference pertains to a *catheter* because both Ullman and Samuels are directed to guidewires. Also, neither reference discloses a structure for holding a shaped distal end of any structure, much less a shaped distal end of a catheter. As discussed above, Ullman utilizes a funnel 18 that allows the distal end of the guidewire 18 to be free floating. Samuels also utilizes a funnel 24 that also allows the distal end of the guidewire 60 to be free floating. *Samuels*, Fig. 3. Thus, it is

respectfully submitted that neither Samuels nor Ullman, either alone or in combination, discloses a sheath "adapted to contain a catheter with a shaped distal tip," as recited in claim 8 and Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 103(a) of claim 8 for this additional reason.

C. The References do not Disclose the Limitations Recited in Claim 15

Claim 15 has been recited above and discussed with reference to Ullman. It is respectfully submitted that Samuels does not cure the above-described deficiencies of Ullman. Specifically, neither Samuels nor Ullman, either alone or in combination, discloses or suggests "a catheter having a shaped distal tip," a tubular enclosure having a length and an inner diameter corresponding, respectively, to a length and outer diameter of the catheter," a first end of the tubular enclosure being adapted to receive the shaped distal tip," a second end of the tubular enclosure being adapted to receive a proximal end of the catheter," and "a hydration opening extending into an interior of the tubular enclosure between the first and second ends thereof, the hydration opening being positioned so that a desired proportion of flow thereinto is directed toward the first and second ends," as recited in claim 15.

Initially, it is noted that neither Samuels nor Ullman is directed toward catheters. As discussed above, both Samuels and Ullman pertain to guidewires. Also, neither the fixed guide 24 of Ullman nor the single hoop packaging tube 40 of Samuels is a tubular enclosure that acts substantially as a sheath (*i.e.*, having a length and an inner diameter corresponding to a

length and outer diameter of the catheter). Because neither Samuels nor Ullman pertain to catheters, specifically a catheter with a shaped distal tip, neither includes a first end adapted to receive a shaped distal tip of the catheter. The funnel 18 of Ullman and the funnel 24 of Samuels allow the distal tip of the guidewire to be free floating. Neither Ullman nor Samuels discloses a second end adapted to receive a proximal end of the catheter. As discussed above, Ullman has no structure to sheath the proximal end of the guidewire. Samuels includes no disclosure that pertains to the proximal end of the guidewire.

Furthermore, as discussed above, Samuels does not disclose or suggest that the adapter 10 or the tube 40 are suitable for hydration. There is no disclosure in Samuels of a hydration opening disposed between the first and second ends of the packaging tube 40. Furthermore, Ullman does not teach that saline solution inserted into the chamber 13 via the filling port 30 is directed in any manner toward the two ends of the chamber 13. That is, as described above, fluid delivered to the isolation chamber 13 via the filling port 30 is never directed toward the entry port 21. Ullman does state that the fluid fills the isolation chamber 13 from the bottom-up, but never discloses or suggests that any fluid would be directed toward the entry port 21. Thus, it is respectfully submitted that neither Samuels nor Ullman, either alone or in combination, discloses or suggests "the hydration opening being positioned so that a desire proportion of flow thereinto is directed toward the first and second ends," as recited in claim 15 and Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 103(a) of claim 15 and claims 16-20 which depend therefrom.

IV. The Rejection of Claims 1, 3, 6-9, 12, 13, 15 and 19 Under 35 U.S.C. § 102(b) as Anticipated by U.S. Patent No. 3,861,395 to Taniguchi Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 1, 3, 6-9, 12, 13, 15 and 19 were rejected under 35 U.S.C. 102(b) as being anticipated by Taniguchi. *9/26/06 Office Action*, p. 11. Taniguchi describes an automatic catheter insertion device assembly 10 consisting of a body 12 and a protective bag 70 extending distally therefrom. *Taniguchi*, col. 3, lines 31 - 41. Taniguchi never describes or suggests any protective package for any medical device. A distal end of the protective bag 70 is freely movable and does not attach to the body 12 in any manner.

B. Taniguchi Does Not Disclose a Protective Package for an Elongated Medical Device as Recited in Claim 1

Claim 1 has been recited above. In the final rejection, the Examiner stated that Taniguchi discloses a protective package for an elongated medical device such as the micro-catheter. *9/26/06 Office Action*, p. 11.

However, Taniguchi is not directed toward a package for a catheter. Instead, Taniguchi pertains to an automated catheter assembly 10 for simplifying catheterization of the urinary bladder. *Taniguchi*, col. 1, ll. 1-4. The assembly 10 is designed to sequentially lubricate portions of the catheter as it is inserted into the body. In fact Taniguchi specifically distinguishes

this device from the protective packaging for the catheter stating:

> In operation, the entire catheter assembly is packaged within a sealed protective envelope (not shown). When it is desired to use the catheter assembly, the latter is removed from its protective envelope.

Taniguchi, col. 3, ll. 42-45.

This is the only reference to a protective package for a catheter in Taniguchi. Taniguchi explicitly pertains to an automated catheter assembly for catherization of either the male urinary bladder or the female urinary bladder. *Taniguchi*, col. 1, ll. 2-5. In contrast, the present invention relates to a protective package for an elongated medical device, such as a catheter.

C. Taniguchi Does Not Disclose a Protective Sheath Including a Lumen Sized to Receive a Body of the Elongated Medical Device as Recited in Claim 1

Claim 1 has been recited above. In the final rejection, the Examiner states that Taniguchi discloses a protective sheath. *9/26/06 Office Action*, p. 11. Even assuming the protective bag 70 equates to a protective packaging for an elongated medical device, the protective bag 70 does not constitute a sheath and clearly does not receive proximal and distal ends of the catheter.

Taniguchi discloses a protective bag 70 used to house a part of a catheter inserted therethrough. However, Taniguchi includes no disclosure in its entirety of the dimensions of the protective bag 70 in relation to the catheter 68. According to Figs. 1 and 11, it appears the

protective bag 70 is a collapsible tube with an inner diameter that is several times the outer diameter of the catheter 68. That is, the protective bag 70 is not a sheath. As discussed above with reference to the 35 U.S.C. § 102(b) rejection of claim 1 over Ullman, a sheath is a "case for a blade...or other instrument *to which it fits closely*." (Webster's Third International Dictionary, 1986). The protective bag 70 does not even encase the entire catheter 68. Taniguchi explicitly discloses that "the open end of a protective bag 70 in which all but the distal end of the catheter is received is supported...." *Taniguchi*, col. 3, ll. 34-41. Furthermore, the Examiner suggests that the body 12 combined with the bag 70 makes up a structure equateable with the recited "protective sheath." Appellants respectfully submit that the body 12 and the bag 70 are separate structures, neither of which can be considered a protective sheath, as recited in claim 1. Thus, Taniguchi does not disclose or suggest "a protective sheath including a lumen sized to receive a body of the elongated medical device," as recited in claim 1.

D. Taniguchi Does Not Disclose a Hydration Opening Disposed Between the First and Second Ends of the Sheath as Recited in Claim 1

Claim 1 has been recited above. In the final rejection, the Examiner stated that Taniguchi discloses a hydration opening (*i.e.*, an unnumbered portion beneath a reservoir 31). *9/26/06 Office Action*, p. 11.

The Examiner stated that Taniguchi shows a reservoir 31 disposed between a proximal end of the body 12 and a distal end of the bag 70. Initially, it should be noted that

Taniguchi does not provide any disclosure with regard to reference numeral 31 and does not include any mention of "a reservoir." Thus, it is unclear to which feature numeral 31 is drawn and what function is performed by this element. Taniguchi does provide, however, that a lubricant bladder 32 is punctured by a spike 33 when a cover 30 enclosing the bladder 32 is depressed. The bladder 32 empties into a transversely enlarged portion 20 of the bore 14 formed in the body 12. The assembly 10 thus lubricates only that portion of the catheter 68 currently received in the transversely enlarged portion 20 and this assembly 10 cannot hydrate the catheter or any other device while proximal and distal ends thereof are received in the assembly 10. That is, the assembly 10 is functional only when the catheter 68 is at least partially extended therefrom. Thus, it is respectfully submitted that Taniguchi does not disclose or suggest a protective sheath "wherein a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of the elongated medical device" in combination with "a hydration opening disposed between the first and second ends of the sheath," as recited in claim 1.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 1 and claims 7, 9, 12 and 13 which depend therefrom.

It is respectfully submitted that claim 15 is also allowable for the same reasons stated above in regard to claim 1. Furthermore, with reference to claim 15 (recited above), Taniguchi further does not disclose "a catheter having a shaped distal tip," "a first end of the

tubular enclosure being adapted to receive the shaped distal tip," and a "hydration opening being positioned so that a desired proportion of flow thereinto is directed toward the first and second ends" of the sheath. As described above, Taniguchi provides fluid only to the transversely enlarged portion 20 and directs no fluid flow to the ends of the catheter 68. Rather, fluid is provided only to a portion of the catheter 68 currently received in the transversely enlarged portion 20 and no flow is directed to the ends of any structure analogous to the recited sheath. Furthermore, such sequential fluid provision requires that the entire catheter 68 be slidable through the bore 14. Thus the transversely enlarged portion 20 and the rest of the bore 14 must be sized to slidably receive the entire catheter 68 and no portion of the bore 14 is adapted to receive a shaped distal tip of the catheter 68. In fact, no shaped distal tip is described or suggested for the catheter 68 and the drawings appear to show an outer diameter and shape of the catheter 68 is substantially constant along its length. *Taniguchi*, Figs. 1 and 3. Because Taniguchi does not disclose a catheter with a shaped distal tip, Taniguchi further does not disclose the first end adapted to receive the shaped distal tip or a hydration opening positioned so that *a desired proportion of flow* thereinto is directed toward the *first* and *second* ends. Accordingly, it is respectfully requested that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 15 and claims 16 and 19 which depend therefrom.

V. The Rejection of Claim 4 Under 35 U.S.C. § 103(a) as Obvious Over Taniguchi in View of U.S. Patent No. 4,805,611 to Hodgkins Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claim 4 was rejected under 35 U.S.C. 103(a) as obvious over Taniguchi in view of Hodgkins. *9/26/06 Office Action*, p. 13. The Examiner stated that Taniguchi discloses the invention substantially as claimed except for a luer or adapter capable of receiving a syringe, but that Hodgkins discloses an adapter 67 for receiving the syringe. *Id.*

B. The References do not Disclose the Subject Matter Recited in Claim 4

Claim 1 from which claim 4 depends has been recited above. Hodgkins discloses an aspirating device consisting of a flexible catheter which is adapted for insertion into the trachea. *Hodgkins*, Abstract. A flexible envelope is connected to the device so that substantially all portions of the catheter between a catheter connector fitting and a proximal opening of the device are within the envelope. *Id.* As such, it is respectfully submitted that Hodgkins does not cure the above-described deficiencies of Taniguchi. Thus, because claim 4 depends from, and, therefore includes all of the elements recited in claim 1, it is respectfully submitted that neither Hodgkins nor Taniguchi, either alone or in combination, discloses or suggests the subject matter

of claim 4.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 103(a) of claim 4.

VI. The Rejection of Claims 1, 3-9 and 11-13 Under 35 U.S.C. § 102(b) as Anticipated by U.S. Patent No. 6,258,072 to Weinberger Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 1, 3-9 and 11-13 were rejected under 35 U.S.C. 102(b) as anticipated by Weinberger. *9/26/06 Office Action*, p. 13. The Examiner stated that Weinberger discloses a protective sheath and a hydration opening as recited in claim 1. *Id.* Weinberger describes a catheter protective device for "protecting the proximal sections of catheters and minimizing blood loss during catheter exchanges." *Weinberger*, col. 1, ll. 5-8. "Typically at the proximal end of the guide catheter there will be a 'Y' adaptor [sic] having two or more manifolds or ports for the introduction of and removal of guidewires, catheters and the like." *Weinberger*, col. 1, ll. 25-28.

B. Weinberger Does Not Disclose a First End of a Sheath Adapted to Receive a Distal End of the Elongated Medical Device and a Second End of the Sheath Adapted to Receive a Proximal End of the Elongated Medical Device as Recited in Claim 1

Claim 1 has been recited above. In the final rejection, the Examiner stated that

the above recitation of claim 1 was disclosed in Weinberger. However, the "Y" adapters of Weinberger remain outside the body while the distal end of the catheter is inserted into the body. Thus, they are expressly designed to cover only a short length of the proximal portion of the catheter and are not designed to hold or protect either the proximal end or the distal end of the catheter. The proximal end of the catheter or guide wire inserted through the "Y" adapter 10 projects proximally beyond the proximal end of the adapter 10 while the distal end of the device 26 extends distally beyond the distal end of the adapter 10 into the body. In this case, it is clear that no fluid injected into the adapter 10 can pass to either end of a catheter received therein. Thus, it is respectfully submitted that Weinberg neither discloses nor suggests a protective package for an elongated medical device, comprising "a protective sheath including a lumen sized to receive a body of the elongated medical device, wherein a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of the elongated medical device," and "a hydration opening disposed between the first and second ends of the sheath," as recited in claim 1.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 1 and claims 3-9 and 11-13 which depend directly or indirectly therefrom.

VII. The Rejection of Claims 1, 3 - 9, 11 - 13, 15, 16, 19 and 20 Under 35 U.S.C. § 102(b) as Anticipated by U.S. Patent No. 5,427,114 to Colliver Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 1, 3 - 9, 11 - 13, 15, 16, 19 and 20 were rejected under 35 U.S.C. 102(b) as anticipated by Colliver. *9/26/06 Office Action*, p. 15. Colliver describes an apparatus for determining pressure at one or a number of intermediate points along a catheter inserted into a closed cavity. Fiberoptic cables extend from the proximal end of the catheter to the intermediate points at which pressure measurements are taken as well as to the distal tip of the catheter. The fiberoptic cables transport light signals from the proximal end toward a flexible, reflective membrane. A pressure sensing coupler interconnects proximal and distal sections of the catheter sheath and also houses the pressure sensor. *Colliver*, abstract.

B. Colliver Does Not Disclose a Protective Package for an Elongated Medical Device as Recited in Claim 1

Claim 1 has been recited above. In the final rejection, the Examiner stated that the Colliver discloses a protective package capable of accommodating an elongated medical device such as internal catheters 30, 32. *9/26/06 Office Action*, p. 15. It is respectfully submitted that Colliver is discloses only a catheter including various internal components and provides no protective package for any elongated medical device. Colliver explicitly discloses a multiple

pressure sensing catheter in its entirety. Colliver never describes or suggests that the multiple pressure sensing catheter 10 serves as a protective package for any device. It is respectfully submitted that those skilled in the art would not conclude that the apparatus disclosed in Colliver could be used in such a fashion. Thus, Colliver neither discloses nor suggests "a protective package for an elongated medical device," as recited in claim 1.

C. Colliver Does Not Disclose a Protective Sheath Including a Lumen Sized to Receive a Body of the Elongated Medical Device as Recited in Claim 1

Claim 1 has been recited above. In the final rejection, the Examiner stated that the above recitation of claim 1 was disclosed in Colliver. Initially, Appellants note that the Examiner does not specify a portion of the apparatus in Colliver purported to constitute a "protective sheath" as recited. Furthermore, the Examiner refers to element 18 as a first end of the sheath when element 18 simply constitutes a vacuum calibration port at a proximal end of the catheter. (*Colliver*, col. 4, ll. 13-16, Fig. 1.). *9/26/06 Office Action*, p. 15. The Examiner further refers to element 28 as a protective first end of the sheath when rejecting claims 3, 6, and 8. *9/26/06 Office Action*, p. 15. However, this element is simply pressure sensor forming the distal end of the catheter. (*Colliver*, col. 4, ll. 43-45, Fig. 1), Therefore, although the Examiner does not clarify how the apparatus of Colliver corresponds to the protective sheath recited in claim 1 the applicant assumes the Examiner is attempting to equate the entire catheter 10 with this claim element.

However, the catheter 10 of Colliver is simply a catheter with multiple internal conduits fixed therein and does not form a protective package for any device. In addition, as stated above, it is respectfully submitted that the term sheath does not encompass any structure into which an item may be inserted. As described above, a parking garage is not a sheath for a car. Rather a sheath is a "case for a blade...or other instrument *to which it fits closely.*" (Webster's Third International Dictionary, 1986). A sheath is not permanently bonded to the item it ensheaths. It is respectfully submitted that the Examiner's reading of Colliver flies in the face of the meaning of the plain language of the claim as well as the entire thrust of the specification of this application. The so called catheters 30, 32 of the device of Colliver are merely internal lumens of the catheter 10 and are permanent fixtures thereof. In addition, these so called catheters 30, 32 are not snugly received within the catheter 10 as seen clearly in each of Figs. 2-5. In fact, by definition, outer surfaces of these lumens 30, 32 must be separated from an inner surface of the catheter 10 so that the infusion of fluids may be carried out via this annular space as will be described in more detail below. That is, fluids injected via the infusion port 14 travel through this annular space not to in any way hydrate the outer surfaces of the lumens 30, 32 as suggested by the Examiner but to leave the catheter 10 via perforations 26 for infusion into the body. Thus, it is respectfully submitted that Colliver neither discloses nor suggests "a protective sheath including a lumen sized to receive a body of the elongated medical device," as recited in claim 1.

Thus, Appellants respectfully request that the Board overturn the Examiner's

rejection under 35 U.S.C. § 102(b) of claim 1 and claims 3-9 and 11-13 which depend directly or indirectly therefrom.

Claim 15 was recited above. It is respectfully requested that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 15 and claims 16, 19, and 20 which depend directly therefrom for the same reasons stated above in regard to claim 15.

D. Colliver Does Not Disclose a Hydration Opening Disposed Between the First and Second Ends of the Sheath as Recited in Claim 1

Claim 1 has been recited above. In the final rejection, the Examiner stated that the above recitation of claim 1 was also disclosed in Colliver. However, it is noted that the so-called inner catheters 30, 32 of Colliver pass through a catheter plug 64 located immediately proximal to the infusion port 14. *Colliver*, col. 5, ll. 53-57, Fig. 5. This catheter plug 64 forms a "hermetic seal so that vacuum calibration may occur via vacuum calibration port 18." *Id.*, col. 5, ll. 58-60. Thus, no fluid can flow past the plug 64 towards the proximal ends of the catheters 30, 32. Furthermore, the distal ends of the catheters 30, 32 are also prevented from contacting fluids inserted via the port 14 as they are sealed within the pressure sensors (*e.g.*, pressure sensor 45). That is, for the sensor 45 to operate properly, the fluid pressure on the proximal side of the diaphragm 51 must remain constant so that fluctuations in the fluid pressure on the distal side thereof will produce known changes in the shape of the diaphragm 51. *See Id.*, col. 6, ll. 1-16. The Examiner stated that the hermetic seal prevents infused fluid from entering into the catheters

but does allow the fluid to flow within the sheath outside the catheters 30, 32. *9/26/06 Office Action*, p. 16. However, this statement has no relevance to the Appellant's argument. Appellants stated that the hermetic seal of Colliver prevents infused fluid from flowing past the plug 64 toward the proximal ends of the catheters 30, 32. Specifically, no fluid flow reaches the proximal ends. Thus, it is respectfully submitted that Colliver neither discloses nor suggests "a hydration opening disposed between the first and second ends of the sheath," as recited in claim 1.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 1 and claims 3-9 and 11-13 which depend directly or indirectly therefrom.

Claim 15 was recited above. Thus, it is respectfully requested that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 15 and claims 16, 19, and 20 which depend directly therefrom for the same reasons stated above in regard to claim 1.

E. Colliver Does Not Disclose a Catheter Having a Shaped Distal Tip as Recited in Claim 15

In the final rejection, the Examiner stated that the above recitation of claim 15 was disclosed in Colliver. *9/26/06 Office Action*, pp. 15-16. However, there is no suggestion that the either of the so-called catheters 30, 32 has a shaped distal tip. Nor would such a tip have any application with these internal lumens 30, 32. Applicants respectfully submit that these so

called catheters in Collver are depicted as of substantially constant cross-section along their lengths. *See Colliver*, Figs. 2-3. Thus, it is respectfully submitted that Colliver neither discloses nor suggests "a catheter having a shaped distal tip," as recited in claim 15.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 15 and claims 16, 19, and 20 which depend directly therefrom for these further reasons.

F. Colliver Does Not Disclose a Hydration Opening Substantially Equidistant between the First and Second Ends as Recited in Claim 20

Claim 20, which depends directly from claim 15, recites a "hydration opening substantially equidistant between the first and second ends." In the final rejection, the Examiner stated that this recitation was disclosed in Colliver, where the first and second ends equate to the vacuum calibration port 18 and distal pressure sensor 28, respectively, of Colliver. However, Colliver shows the infusion port 14 distant from the distal pressure sensor 28 in which the distal end of the catheter 30 is located and almost immediately proximal to the catheter adapter 40 at which the proximal ends of the catheters 30, 32 are located. There is no specific reference to the positioning of the infusion port 14 with respect to the ends of the inner catheters 30, 32 and this indication in the drawings teaches away from the recited "equidistant" positioning. Furthermore, as this port 14 is directed only to infusing fluids to the body via perforations 26, it is respectfully submitted that one skilled in the art would not have been motivated to adjust the position of the

port 14 to such an equidistant position. In fact, it is preferable that such a port remain outside the body while the perforations are in a desired location within the body. Thus, the motivation of Colliver is to provide the port 14 as far proximally as possible. It is therefore respectfully submitted that Colliver neither discloses nor suggests a "hydration opening substantially equidistant between the first and second ends," as recited in claim 20.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 20 for this further reason.

8. Conclusions

For the reasons set forth above, Appellants respectfully request that the Board reverse the final rejections of the claims by the Examiner under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) and indicate that claims 1 - 21 are allowable.

Respectfully submitted,

Date: June 1, 2007

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CLAIMS APPENDIX

1. (Rejected) A protective package for an elongated medical device, comprising:

a protective sheath including a lumen sized to receive a body of the elongated medical device, wherein a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of the elongated medical device; and

a hydration opening disposed between the first and second ends of the sheath.

2. (Rejected) The protective package according to claim 1, wherein the sheath is formed as a hoop and wherein the medical device is a catheter.

3. (Rejected) The protective package according to claim 1, further comprising a protective assembly disposed at the first end of the sheath, the protective assembly being adapted to maintain a desired shape of the distal end.

4. (Rejected) The protective package according to claim 1, further comprising a luer attached to the sheath in fluid contact with the lumen, the luer defining the hydration opening.

5. (Rejected) The protective package according to claim 1, further comprising an adapter coupled to the hydration opening for receiving a syringe.

6. (Rejected) The protective package according to claim 3, wherein the protective assembly is adapted to prevent damage to a curvature of the distal end of the elongated medical device.

7. (Rejected) The protective package according to claim 1, wherein the sheath is adapted to contain one of a catheter, a guide wire and a medical coil.

8. (Rejected) The protective package according to claim 6, wherein the sheath is adapted to contain a catheter with a shaped distal tip.

9. (Rejected) The protective package according to claim 1, wherein the hydration opening is adapted to divide a flow of the fluid thereinto to achieve a desired ratio of fluid flow at the first end to fluid flow at the second end.

10. (Rejected) The protective package according to claim 9, wherein the desired ratio is one to one.

11. (Rejected) The protective package according to claim 1, wherein the hydration opening is substantially equidistant from the first and second ends.

12. (Rejected) The protective package according to claim 1, wherein the hydration opening is oriented to direct an amount of flow toward the first end which is different than an amount of flow directed toward the second end.

13. (Rejected) The protective package according to claim 12, wherein the hydration opening is positioned so that, the difference in the amounts of flow toward the first and second ends achieves a desired ratio of fluid flow at the first end to fluid flow at the second end.

14. (Rejected) The protective package according to claim 13, wherein the desired ratio is one to one.

15. (Rejected) A catheter kit comprising:

a catheter having a shaped distal tip;

a tubular enclosure having a length and an inner diameter corresponding, respectively, to a length and outer diameter of the catheter;

a first end of the tubular enclosure being adapted to receive the shaped distal tip;

a second end of the tubular enclosure being adapted to receive a proximal end of the catheter; and

a hydration opening extending into an interior of the tubular enclosure between the first and second ends thereof, the hydration opening being positioned so that a desired proportion of flow thereinto is directed toward the first and second ends.

16. (Rejected) The catheter kit according to claim 15, further comprising a protective structure disposed at the first end, the protective structure maintaining a desired curvature of the shaped distal tip.

17. (Rejected) The catheter kit according to claim 15, wherein the tubular enclosure is coiled to form a hoop.

18. (Rejected) The catheter kit according to claim 15, wherein a hydrating fluid introduced into the tubular enclosure via the hydration opening is divided such that the proximal end and the distal end of the catheter are substantially equally hydrated.

19. (Rejected) The catheter kit according to claim 15, wherein the catheter is a micro-catheter with a shaped distal tip.

20. (Rejected) The catheter kit according to claim 15, wherein the hydration opening is substantially equidistant between the first and second ends.

21. (Rejected) A protective package for removably receiving an elongated medical device, comprising:

a protective sheath including a lumen sized to tightly fit a body of the elongated medical device to be received therein, a first end of the sheath being adapted to receive a distal end of the elongated medical device and a second end of the sheath being adapted to receive a proximal end of the elongated medical device; and

a hydration opening disposed between the first and second ends of the sheath so that fluid supplied to the sheath via the hydration opening is provided to the first and second ends of the sheath.

EVIDENCE APPENDIX

No evidence has been entered or relied upon in the present appeal.

RELATED PROCEEDING APPENDIX

No decisions have been rendered regarding the present appeal or any proceedings related thereto.